MolDX® General FAQs

Program Overview

1. What is the purpose of the MolDX® Program (Administered by Palmetto GBA®)?

To identify molecular diagnostic tests, determine coverage, and determine reimbursement on behalf of the Medicare program.

2. What is the DEX® Diagnostics Exchange's involvement in the MolDX Program?

MolDX uses the DEX Registry as a critical business process. The DEX Registry is used to track accurate information about molecular diagnostic tests and allow for the application of appropriate payer controls in claim adjudication.

3. What is the purpose of the DEX Z-Code®?

The Z-Code is a unique identifier that clearly identifies the test being performed on a claim, allowing the payer to know exactly what service was rendered. Providing the Z-Code on a claim, with the appropriate Recommended CPT® Code, may reduce the administrative burden labs may encounter surrounding billing for these services as it provides a means for the payer to automate adjudication or pre-authorization of claims. The code allows the payor to reproducibly and reliably assess medical necessity based on registered test information (such as intended use, methodology, and performance).

4. How does this program help claim adjudication?

Once the required information is received and a DEX Z-Code® identifier is assigned, coverage and reimbursement will be assigned to the Z-Code. This simplifies the claim submission process and ensures consistent and accurate adjudication of claims.

5. What laboratories will be affected?

All private, reference, and hospital laboratories that perform molecular diagnostic testing and submit claims to Medicare in JE, JF, JJ, JM, J15, J5 or J8 on forms CMS 1500 (Part B), UB04 (Part A) or electronic claims on a 5010-837P (Part B) or 837I (Part A) are affected by this program. (Please reference the specific jurisdiction MDT policy for effective dates.)

6. Is the MolDX Program national in scope?

No. Medicare contractors (MACs) participating in the MolDX® Program are:

- **JM** A/B (N.C., S.C., Va., W.Va.) and **JJ** A/B (Tenn., Ga., Ala.) administered by Palmetto GBA.
- **JE** A/B (American Samoa, Calif., Guam, Hawaii, Nev., North Marina Islands) and **JF** A/B (Alaska, Ariz., Idaho, Mont., N.D., Ore., S.D., Utah, Wash., Wyo.) administered by Noridian Healthcare Solutions.
- **J5** A/B (Iowa, Mo., Kan., Neb.) and **J8** A/B (Mich., Ind.) administered by WPS Government Health Administrators.
- **J15** A/B (Ky., Ohio) administered by CGS Administrators, LLC.

The roll out of JJ by Palmetto GBA began in early 2018. Labs that perform services for patients in those states were notified to begin DEX Z-Code registration. Claims submitted after June 1, 2018, must have a Z-Code.

7. Which molecular diagnostics tests/CPT® codes are within scope for obtaining a DEX Z-Code?

The scope of the MolDX Program is outlined in LCD MolDX: Molecular Diagnostic Tests (MDT) (L35025) and the associated Billing and Coding articles: Billing and Coding Article MolDX: Molecular Diagnostic Tests (MDT) (A56853) and Article - Billing and Coding: MolDX: Proteomics Testing (A59636).

For questions about specific tests/assays not described above, please Contact Us.

8. After a test is granted a DEX Z-Code, can a hospital bill their respective MAC directly for the test using the assigned Z-Code?

Yes. Effective March 1, 2017, hospitals must add the DEX Z-Code in block 80 of the UB04 claim form or on line SV202-7 of the 837I electronic claim.

9. Are hospital labs that file institutional claims and providers that file professional claims exempt from the requirement to obtain a DEX Z-Code?

Providers submitting institutional claims are required to submit claims with DEX Z-Codes. Physicians submitting professional claims (-PC or -26) are not required to use DEX Z-Codes.

10. Who are the Medicare Administrative Contractor (MAC) Medical Directors of Palmetto GBA?

Gabriel Alejandro Bien-Willner, MD, PhD, is the Medical Director of the MolDX program at Palmetto GBA, which seeks to understand the molecular testing landscape to implement payer controls and coverage, and to set policy. He is a leader in the Precision Medicine space and practices as a board-certified Anatomic Pathologist and Molecular Genetic Pathologist. Dr. Bien-Willner received his MD and PhD from Baylor College of Medicine, with a doctorate in Human Molecular Genetics. His clinical training and academic tenure were at Washington University in St. Louis. Throughout his career, he has been active in research, development and advancement of molecular diagnostic services, specifically next-generation sequencing. His experience spans both academia and industry. He has worked closely with clinicians to develop clear clinical diagnostic and treatment pathways directing Precision Medicine programs for community cancer centers.

Angella Charnot-Katsikas, MD, FCAP, is a Medical Director for the MolDX program at Palmetto GBA. She is a board-certified Clinical Pathologist, Medical Microbiologist, and Molecular Genetic Pathologist with additional fellowship training in Clinical Medical Ethics. Dr. Charnot-Katsikas received her MD degree from Rush Medical College in Chicago, and then completed her residency and fellowship training at the University of Chicago, where she later served as an Associate Professor of Pathology. She has served as the Medical Director of multiple hospital and community-based laboratories and has led numerous research, education, quality, and diagnostic stewardship initiatives throughout her career.

Magdalena Jurkiewicz, MD, PhD, MPH, is a Medical Director for the MolDX program at Palmetto GBA. She is a board-certified Clinical and Molecular Genetic Pathologist. Dr. Jurkiewicz received her MD and PhD degree in Genetics from SUNY Stony Brook following completion of the Medical Scientist Training Program. She also holds an MPH from the Yale School of Public Health and completed her residency and fellowship training at New York-Presbyterian Hospital/Columbia University in New York City. She has authored numerous research articles in the field of human genetics and molecular diagnostics and has clinical industry experience as a laboratory director of oncology and molecular pathologist.

Megan Landsverk, PhD, MB(ASCP)^{CM}, FACMG, is a Director for the MolDX program at Palmetto GBA. She is a board-certified Molecular Geneticist. Dr. Landsverk received her PhD in Biochemistry and Molecular Biology from Baylor College of Medicine, received postdoctoral training in Medical Genetics at the University of Washington and completed her molecular genetics fellowship training at Baylor College of Medicine. She has served as a laboratory director in several clinical genetics laboratories, has held multiple academic faculty positions and has numerous publications in the field of genetics.

Jacqueline Lekostaj, MD, PhD, is a Medical Director for the MolDX program at Palmetto GBA. She is a board-certified Anatomic and Clinical Pathologist and Molecular Genetic Pathologist. Dr. Lekostaj received her MD and PhD in Tumor Biology from Georgetown

University. She completed her residency at Northwestern Memorial Hospital in Chicago and fellowship training at the University of Iowa Hospitals and Clinics in Iowa City. She has experience in clinical industry as a molecular pathologist and laboratory director, specializing in molecular oncology.

Registration Topics

1. How does a lab register in DEX® to obtain Z-Codes®?

Visit the DEX Diagnostics Exchange Registry and select 'Register as a Lab or Hospital' on the log in page. Complete the registration form to gain access to the DEX Registry. If you receive a notification that your organization's NPI# or CLIA# is already registered, please contact DEX.Customer.Service@PalmettoGBA.com for assistance.

2. How many users can register per organization?

An organization can have two (2) registered users. A registered user for an organization gets a username that is specific to the contact person designated by each laboratory. Please do not forward or share this information. Other colleagues within your organization who want to register, may apply for a public user account. A public user account allows viewing of public information, which does not include Z-Codes.

3. Are DEX Z-Codes visible if I register as a public user?

DEX Z-Codes are not publicly visible. Public users may register in DEX and view test details that are publicly available which may include coverage and price information assessed by the MolDX® Program.

4. What lab test information submitted will be made available to public users in the DEX Diagnostics Exchange Registry?

The following fields are visible to public users of the DEX Registry: test name, lab test ID, lab/manufacturer name, lab test description, FDA 510(k)/PMA status and associated FDA document number, handling instructions, turnaround time, specimen information, patient instructions, MolDX Price, and MolDX Coverage determination. DEX Z-Codes are *not* publicly available.

As an administrator in the DEX Registry, you will be able to control privacy for other fields for your tests under your Organization's Test Privacy settings.

5. What if I do not perform the test, but I need the Z-Code from my reference lab for billing purposes?

Both the performing lab and client lab must register as an organization in DEX Registry. Only the performing lab needs to add the test to obtain a Z-Code. The client lab will need an approved Sharing request from the reference lab to obtain the Z-Code for the send out test(s). More information on using the Sharing feature can be found in the DEX Administrator FAQs (PDF).

Test Submission Requirements

1. Once registered as a user, how do I add my tests to the registry?

Select the 'Add Test' action button from the Catalog Overview or My Diagnostics Exchange tabs within DEX®. Complete all required fields and submit for review. For more information, see the DEX Diagnostics Exchange Help Files.

2. How can I reduce delays in obtaining a Z-Code®?

When adding a test, use the tooltip buttons to identify required information and view helpful hints. For example, the Test Description should succinctly describe the test's intended use, indications for ordering, and limitations. PGx tests should include the intended drug(s) of interest in the description.

3. If multiple tests may be performed and billed within one assay, is the lab required to separately register each test within the assay?

A DEX Z-Code identifier application is required for a single assay that may involve multiple tests in order to produce a single result. Ensure you enter your test as it is orderable to providers on your test requisition. A DEX Z-Code is assigned to individual orderable tests and/or panels and not to CPT® codes.

4. If a lab performs the same exact test in two different locations, operating under two different CLIA numbers, will the lab be required to submit both tests for unique identifiers?

If the test process is standardized and the same method is used to acquire results in both locations, lab will only have to submit one application for the test. However, if there is a difference in the method, a separate application will be required for both locations.

5. If my lab makes changes to a test after a Z-Code is assigned, should I apply for a new Z-Code?

It is not necessary to apply for a new Z-Code when you make changes to a test. Please log into DEX and update the existing test record with the new information. If the changes are significant enough to constitute a new test, such as a methodology change or additional specimen types, a new Z-Code may be assigned.

6. Our lab no longer performs a test, should I retire it in the DEX Registry?

Yes, in the event a test is retired, please update your DEX test submission to reflect this change. The DEX Registry relies on accurate data entry and maintenance. Please review the DEX Administrator FAQs (PDF) for specific instructions.

7. Are labs required to register tests that use a code in the molecular diagnostics (MDx) code range and a code that is not listed in the MDx range of codes?

Yes, labs must register tests that include MDx and non-MDx range of codes in the test panel.

8. Is a Z-Code required for FDA-approved/cleared tests or modified FDA-approved/cleared kits?

Yes, a Z-Code is required in both scenarios* but the process may differ for obtaining the Z-Code (see #9). The FDA approval and clearance processes ensure only the clinical and analytical validity of the test. The FDA does not include clinical utility in their review, which is required for a technical assessment.

*NOTE: For FDA-approved/cleared molecular syndromic panels for infectious disease pathogen identification testing, please refer to:

- LCD MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988)
- Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A58710)
- FAQ for Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (PDF)

9. Should the manufacturer or the performing lab add an unmodified FDA-approved/cleared in vitro diagnostic test kit to the DEX Registry?

If the test is within scope of the program requirements, then both the manufacturer and the performing lab should register their organization in DEX. The manufacturer should follow the steps to add the test and obtain the Z-Code. Once that is complete, the performing lab can obtain the Z-Code through the Sharing function within the DEX Registry.

If a performing lab *modifies* an FDA-approved/cleared test in any way from its intended use labeling, the resulting test is considered a LDT (laboratory developed test) and the performing lab will need to add the test to the DEX Registry themselves.

10. How do I obtain a DEX Z-Code for an unmodified FDA-approved/cleared test my lab is performing?

The Z-Code can be obtained through the *Sharing* functionality in DEX if the following conditions are met:

- The test is within scope of the program requirements.
- The test performed is FDA-approved/cleared and unmodified. *Note: If the test is being used in ways not consistent with its intended use labeling, then it is considered modified, and Sharing cannot be used.*
- The manufacturer of the test has registered in DEX and received a Z-Code.
- Your organization is registered in DEX.

If these conditions are met, then you can Request Sharing with the manufacturer in the DEX Registry and access the DEX Z-Code.

If the manufacturer has not registered or added the test and therefore you are unable to use the Sharing function, then your organization may need to add the test. Contact DEX for assistance.

11. If the kit used in a LDT is not FDA-approved/cleared, should the lab apply for a Z-Code for that kit?

Yes, an application for a Z-Code identifier will be required if the test has a CPT® code within scope for requiring a DEX Z-Code.

12. If a test is pending FDA-approval/clearance, should the laboratory provide the pending number in the submission?

We recommend the laboratory wait until the FDA determination is complete to add that information to your test in DEX.

13. How is algorithm defined in the test review?

An algorithm may be considered a meaningful and independent component of a laboratory process when ALL the following conditions are met:

- It is an unambiguous problem-solving operation that includes deploying a set of rules or calculations requiring computer processing;
- The test result (or a component of the result) is the calculated output of this process, and not an intermediary process;
- The same or similar test result could not be obtained without the use of this process;
- The input for the computation is derived from biological samples using analytical processes, and must include data from the sample submitted for the test;
- The process must:
    - Either be required for the analytical result, OR
    - If adjunct to the analytical result as a post-analytical process, the calculation itself must be independently found to be reasonable and necessary apart from the other components of the test.

Technical Assessment (TA) Evaluation

1. How will I know if my test needs additional Technical Assessment (TA) documentation?

If additional documents are needed for the TA, you will be notified by email. Once notified, please submit all completed documentation within 15 calendar days. In general, additional documentation is needed for more complex testing. For example, NGS-based tests require additional documentation and form submission.

2. Can I still submit Technical Assessment (TA) documentation if I miss the submission deadline?

We recommend completing all aspects of test validation prior to registering for a Z-Code® to prevent delays. If the 15-day deadline is missed, your test will not have demonstrated compliance with relevant standards and by default will be considered Not Successful. However, you may submit your technical assessment documentation at any time after the deadline for review.

3. Where should I send the requested Technical Assessment (TA) documentation?

Please refer to the Technical Assessment page for information on where to submit requested TA documents.

4. Why was my Technical Assessment (TA) Result updated to Not Successful?

Tests will be updated with a TA Result of Not Successful for the following reasons:

- The TA documentation submitted does not demonstrate analytical validity, clinical validity, and/or clinical utility per established TA evaluation procedures.
- The requested TA documentation was not received.
- The type of service submitted has not been established to have medical necessity.

For billing/claims related inquiries, please contact the participating payer.

Claims Related

1. I received email notification with assigned Z-Codes® for my tests, when can I put them on a claim?

After DEX® assigns a Z-Code for a specific test, a Technical Assessment (TA) is performed, and a result determined at the completion of the assessment. The Z-Code is effective and can be submitted on claims once the test has been assigned a TA result and has been assigned a recommended CPT® code.

- For tests that do not require additional TA documentation, this is complete in approximately 3-4 weeks.

- For tests that have submitted additional TA documentation, this process can take up to 60 days.

2. When will my test be updated with a Technical Assessment (TA) result in the DEX Registry?

Once the TA review process is complete, you will receive an email notification and the TA evaluation result will be updated in the DEX Registry.

3. Who should I contact with claim issues related to a Z-Code?

MolDX is not able to address claims related questions. Please contact your payer MAC directly for assistance.

4. Will ABNs be valid with the DEX Z-Code identifier?

The DEX Z-Code identifier is only additional information, not a billing code.

5. Will MolDX pay test services provided prior to the Technical Assessment (TA) approval date?

MolDX will reimburse tests that fulfill coverage criteria in valid policy, which requires successful completion of a TA and a valid Z-Code submitted with the claim. The effective date for reimbursement will be the date the successful TA was received by MolDX. Labs are instructed to hold claims during the TA review period. If the TA is successful, you can be reimbursed for services performed during the review period.